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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,075	06/20/2003	Michael P. Boutillette	BSME120588	8875

26389 7590 08/09/2006

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EXAMINER

STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,075

Applicant(s)

BOUTILLETTE ET AL.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 8 recite the limitation "the forward facing surface ". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Swick (3,584,625). Swick clearly discloses a tool that includes all of the limitations as recited in claim 1. Swick clearly shows a tool comprising a handle (20) with a pin (14) that is secured to the handle and is sized to fit in within a guidewire channel and can engage a guidewire and a web (18) that secures the pin to the handle wherein in the web can fit through a slot of a guidewire channel to allow the pin to be moved along the guidewire

channel by the handle, wherein the forward facing surface of the web is substantially blunt to prevent cutting the catheter, and wherein the pin (14) is capable of engaging a guidewire and lifting it up.

In regards to claim 2, Swick clearly discloses a tool that includes all of the limitations are recited in claim 1 wherein the pin (14) has a tapered end that is capable of engaging a guidewire.

In regards to claim 3, Swick clearly discloses a tool that includes all of the limitations are recited in claim 1 wherein the web has a thickness that is smaller than that of the diameter of the pin (14).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Huggins (3,610,239). Huggins clearly discloses a tool that includes all of the limitations as recited in claim 1. Huggins clearly shows a tool comprising a handle (18) with a pin (14) that is secured to the handle and is sized to fit in within a guidewire channel and can engage a guidewire and a web (22) that secures the pin to the handle wherein in the web can fit through a slot of a guidewire channel to allow the pin to be moved along the guidewire channel by the handle, wherein the forward facing surface of the web is substantially blunt to prevent cutting the catheter, and wherein the pin (14) is capable of engaging a guidewire and lifting it up.

In regards to claim 2, Huggins clearly discloses a tool that includes all of the limitations are recited in claim 1 wherein the pin (14) has a tapered end that is capable of engaging a guidewire.

In regards to claim 3, Huggins clearly discloses a tool that includes all of the limitations are recited in claim 1 wherein the web has a thickness that is smaller than that of the diameter of the pin (14).

Claims 1-2, 4-5, and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski (5,364,376). Horzewski clearly shows a guidewire exit tool that includes all of the limitations as recited in claims 1. See Figures 1 and 2 and the respective portions of the specification. Horzewski shows a guidewire exit tool with a handle (25) with a pin (32) secured to the handle and is sized to fit in within a guidewire channel, and a web (24) that secures the pin to the handle wherein the web fits through a slot of a guidewire channel to allow the pin to be moved along the guidewire channel, wherein the forward facing surface of the web is substantially blunt to prevent cutting the catheter, wherein the pin engages a guidewire and lifts an end of the guidewire out of a guidewire channel.

In regards to claim 2, the pin (24) has a tapered end (26) that is designed to engage a guidewire and lift it out of the guidewire channel of a rapid exchange catheter.

In regards to claims 4-5, Horzewski clearly shows a guidewire exit tool that includes all of the limitations as recited in claims 1 wherein the handle (25) has an oval configuration with a round configuration at the proximal end of the handle (25) which tapers to a more narrow configuration at the distal end of the handle (25). See Figure 1.

Horzewski clearly discloses a method of using a guidewire that includes all of the limitations as recited in claims 8-11. Horzewski discloses a method of using a guidewire in which a guidewire is loaded from the distal end of the catheter and passed to the

proximal end of the catheter where the proximal end of the guidewire engages the tapered end (26) of the guidewire tool, which lifts the proximal end of the guidewire out of the guidewire lumen (16). See col.4, lines 10-18.

In regards to claim 9, the pin (24) has a tapered end (26).

In regards to claim 10, the guidewire exit tool is placed in the distal end of the guidewire channel (16) and slides until it reaches the aperture (20) where it engages the guidewire.

In regards to claim 11, the proximal end of the guidewire engages with the tapered end (26) of the guidewire exit tool as the guidewire is loaded and slid from the distal end of the catheter to the proximal end of the catheter.

In regards to claims 12-13, the pin is rounded such that the forward portion of the pin has a solid, elliptical surface (74) disposed at an angle that will engage the guidewire to lift it through the slot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swick (3,584,625) or Huggins (3,610,239). Swick and Huggins meet the claim limitations as described in claim 1 but fail to disclose the handle having an oval shape with a recessed center, opposing sides, and an annular rim. At the time the invention was made, it would have been an obvious matter of design choice to choose this configuration for the handle. The Applicant has not disclosed that this configuration serves any advantage or solves a stated problem. Furthermore, in the final paragraph of the specification, the Applicant discloses that a "conventional handle" could be used with the present invention. Therefore, it would have been prima facie obvious to modify Swick and Huggins to obtain the invention as specified in claims 4-7 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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